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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,021	01/08/2001	F. Ivy Carroll	2025-0178-0	3556
22850	7590	10/09/2003	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			TRUONG, TAMTHOM NGO	
		ART UNIT	PAPER NUMBER	
		1624	14	
DATE MAILED: 10/09/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/755,021	CARROLL ET AL.
	Examiner Tamthom N. Truong	Art Unit 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 June 2003.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-11, 13-17, 19-21 and 23-25 is/are rejected.
- 7) Claim(s) 12, 18, and 22 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.      6) Other:

## DETAILED ACTION

Applicant's amendment of 6-11-03 has been considered. The insertion of the word "or" in the appropriate place has overcome the objection to the specification as well as the 112/2<sup>nd</sup> rejection for claims 1, 7, and 13. Also, the phrase "as indicated above" or "as noted above" has been deleted from claims 3-5, 9-11, and 15-17. Thus, the 112/2<sup>nd</sup> rejection for said claims is withdrawn as well. Applicant's argument has also rendered moot the 112/2<sup>nd</sup> rejection for claims 6, 12, and 18.

Claims 1-21 are pending along with new claims 22-25. It is acknowledged that new claims are drawn to the elected subject matter, and no new matter is introduced.

The following new 112/1<sup>st</sup> and 2<sup>nd</sup> issues are noted, and therefore, the rejection is made non-final.

### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-5, 7-11, 13-17, 19-21, and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claims 1, 7, and 13 recite the definitions of R<sub>8</sub>-R<sub>14</sub> to include "*CH<sub>2</sub> aryl substituted by one or more substituents Y<sub>1</sub>*," or

“ $CH_2(CH_2)_nY_2$ ”. However,  $Y_1$  and  $Y_2$  are defined in terms of  $R_8-R_{14}$ . Thus, it is unclear as to the metes and bounds of  $R_8-R_{14}$ ,  $Y_1$ , and  $Y_2$ .

2. Dependent claims 2-5, 8-11, 14-17, and 19-25 are rejected since they carry over variables  $R_8-R_{14}$ ,  $Y_1$ , and  $Y_2$ .

***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. **Lack of Written Description:** Claims 1-6, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a “method of binding a kappa opioid receptor in a subject in need thereof”. In the specification, said method is described as being related to various addictions as well as diseases of different etiologies. Many of the listed diseases are not linked to the alleged activities. For example, the specification states:

*The compounds of the present invention may also be used as cytostatic agents, as antimigraine agents, . . . , as virucides, to treat diarrhea, as antipsychotics, as antischizophrenics, as antidepressants, . . . ,*

*as anti-smoking agents, to treat alcoholism, ....,*

It is not known in the pharmaceutical art, to use “antimigraine agents” or “cytostatic agents” to treat diarrhea. Similarly, how can “anti-smoking agents” treat alcoholism. Such a description of the claimed method appears to contradict with the basic pharmaceutical science.

4. **Lack of Enablement:** Claims 1-6, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claimed method encompasses the treatment of many diseases that simply cannot be treated by kappa opioid antagonists due to their divergent pathophysiologies, and various effected organs or tissues. Furthermore, as discussed above, many of the alleged activities such as cytostatic, antimigraine, virucides, anti-smoking are not shown as linked to kappa opioid receptor. Another words, there is no data to allow one skilled in the art to draw conclusion on the binding of kappa opioid receptor to said activities. Therefore, because of the unpredictable nature of the art, undue experimentation would be required for one skilled in the art to practice the claimed method in a clinical setting.

#### *Claim Objections*

5. Claims 12, 18, and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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6. This application contains claims 1-5, 7-11, and 13-17 having subject matter that was not elected in Paper No. 8. A complete reply to this rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (7 am -12 pm, and 3 pm - 6 pm) starting from 10-1<sup>st</sup>-03).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

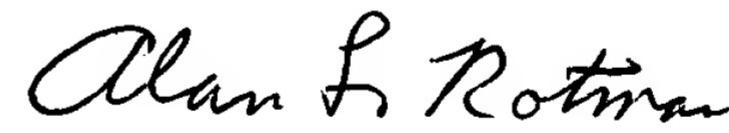
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

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October 8, 2003



ALAN L. ROTMAN  
SUPERVISORY PATENT EXAMINER  
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